Remarks

Applicants have amended the title as forth in the attached Appendix.

Claim 1 is currently pending in this application. Applicant has cancelled claim 1 without disclaimer or prejudice to the subject matter contained therein. Applicant reserves the right to file one or more continuation applications directed to this subject matter.

Applicant has added new claims 33-86. Support for these claims may be found in the specification and claims as a whole, and specifically as follows:

New Claims	Specification	Originally Filed Claims in Parent
33, 34, 35, 36, 42, 43, 44, 45, 46, 47, 48, 56, 57, 58, 59, 65, 66, 67, 68, 69, 72, 73, 74, 75, 76, 81, 82	Page 1, lines 15-22 "The indicators of menopausal symptoms according to Greene and Cooke comprise hot flushes, sweating at night, heart beating quickly or strongly, feelings of tension or nervousness, difficulty in sleeping, excitability, attacks of panic, difficulties in concentrating, feelings of tiredness or lack of energy, unhappiness or depression, crying spells, irritability, feelings of dizziness or faintness, pressure or tightness in head or body, parts of the body feeling numb or tingling, dry vagina and/or dry mouth, headaches, muscle and joint pains, loss of feeling in hands or feet, breathing difficulties, and loss of interest in sex. Page 8, lines 1-7. "The present invention provides in a first aspect a method for the treatment or prevention of menopausal symptoms or osteoporosis wherein there is administered to a subject in need of such treatment a therapeutically effective amount of the isoflavone formononetin, or a method for the treatment or prevention of menopausal symptoms wherein there is administered to a subject in need of such treatment a therapeutically effective	1, 6, 18, 19

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New Claims	Specification	Originally Filed Claims in Parent
	amount of the isoflavone daidzein, the isoflavone being optionally administered with one or more pharmaceutically acceptable adjuvants, carriers and/or excipients." Page 9, lines 20-30. "Formononetin or daidzein are preferably administered to a subject substantially unaccompanied by other isoflavones. By this is meant that any composition or preparations may contain minor amount of other isoflavones, in the order of 10% (w/w) or less. Preferably the formononetin or daidzein represents at least 90% of isoflavone content, more preferably 95%, even more preferably 98% or more. Genistein, if present, is in amounts of about 5% or less, more preferably less than 1% (w/w) with regard to isoflavone content. It is recognized by regulatory agencies that an isoflavone content in the order of 95% of total isoflavones represents effective purity. In the treatment of menopausal symptoms formononetin may be administered in combination with daidzein, for example from a ratio of 1:10 to 10:1. Page 10, lines 12-13. "Daidzein and/or formononetin compositions or preparations are administered in an amount, and under a dosage regime which gives relief to menopausal symptoms... ." Page 18, lines 1 and 2 "15 post-menopausal women who are experiencing menopausal symptoms are each administered 60 mg formononetin daily for three months. Relative to a control group the treatment group show a significant decrease in Greene Score for menopausal symptoms." Page 18, lines 14-16 "The second study (double-blind, placebo-controlled)	

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New Claims	Specification	Originally Filed Claims in Parent
	involved a six month study of the effects of phytoestrogen formononetin on bone resorption markers in twenty post-menopausal women."	
37, 38, 39, 49, 50, 51, 60, 61, 62	Page 10, lines 12-20 "Daidzein and /or formononetin compositions or preparations are administered in an amount and under a dosage regime which gives relief to menopausal symptoms or osteoporosis. With regard to menopausal symptoms this can be readily determined by the subject who is being treated, or by their physician. Generally, it is found that prevention or therapy of menopausal symptoms and osteoporosis results from daily administration of formononetin such as from one to six times in a 24 hour period, as does the treatment or prevention of menopausal symptoms with daidzein, so as to give a daily dose of the isoflavone in an amount from about 5 mg to about 400 mg per day (this dosage range may be referred to as the "effective amount")."	7, 8, 9, 20
40, 52, 63, 70, 77, 83	Page 10, lines 21-26 "Formononetin and daidzein may be prepared by synthesizing the compounds by conventional chemical synthetic techniques as are well known in the art, or by purification from extracts of plants of the genus ..."	10
41, 53, 64, 71, 78, 84	Page 8, lines 1-7 "The present invention provides in a first aspect a method for the treatment or prevention of menopausal symptoms ..., a therapeutically effective amount of the isoflavone formononetin, ... or ...a therapeutically effective amount of the isoflavone daidzein, the isoflavone being optionally administered with one or more pharmaceutically acceptable adjuvants, carriers and/or excipients." Page 10, lines 28 through page 11, line 1. "Compositions/preparations administered to subjects for the treating and/or prevention of, or for reducing the predisposition to, menopausal symptoms or osteoporosis may comprise in addition to the specific isoflavones	1

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New Claims	Specification	Originally Filed Claims in Parent
	previously mentioned formononetin optionally administered with one or more pharmaceutically acceptable adjuvants, carriers and/or excipients, so as to form a composition or preparation."	
54, 79, 85	Page 10, lines 1-4 "Daidzein metabolites may be used in place of daidzein in the various embodiments of this invention. These metabolites include equol, 0-desmethylangolensin (ODMA), dehydroequol, 2-dehydro-ODMA, 6-hydroxy-ODMA, dihydrodaidzein and tetra-hydrodaidzein ...."	13, 21
55, 80, 86	Page 15, lines 1-2 "Daidzein or formononetin may also take the form of aglycones, glycosides, malonyl or acetyl derivatives."	31

Thus, claims 33-86 are fully supported by the specification and are now pending.

Claim Rejections Under 35 U.S.C. § 102 (b)

The Office rejects Claim 1 under 35 U.S.C. 102(b) as being anticipated by Gorbach et al, U.S. Patent 5,498,631 ("'631"). The Office characterizes the '631 patent as teaching compositions and methods of treatment with daidzein or formononetin. The Office also rejects claim 1 as anticipated by WO 93/23069 ('069), arguing that the '069 teaches compositions comprising formononetin and daidzein, as specified in a ratio of 2:1 to 1:2 and discloses the treatment of menopause symptoms. Given that Applicant has cancelled claim 1, the rejections are now moot.

In order to expedite prosecution, however, Applicant acknowledges the Office's previous remarks in the parent case regarding claims directed towards menopausal symptoms. Thus, Applicant wishes to direct the Office's attention, i.e., to Interference

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Proceeding No. 104,576 involving the very two documents cited above, the Gorbach '631 patent and the '069 application which is a counter part ot the US. application in interference, Serial No. 08/910,837. In that interference, Stanley Gorbach was the senior party. The junior party, Graham Edmund Kelly, the present inventor in this application, successfully argued the priority of U.S. Application Serial No. 08/910,837. This application is a counterpart to the '069 reference cited by the Office above.

In the interference, the '069 reference was awarded priority, indicating that the invention embodied in those claims was invented prior to the date of invention of the Gorbach '631 patent. Thus, to the extent that the presently pending claims are similar to the Kelly claims in the interference, the '631 Gorbach patent is not a proper reference under Section 102.

The present claims differ from the Kelly claims in interference, *inter alia*, because they expressly limit the amount of genistein. Gorbach does not teach the exclusion of genistein, and, accordingly, Gorbach cannot be a § 102 (b) reference. As is well known, "for a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference." M.P.E.P. § 2131.

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Conclusion

Applicant submits that all pending claims 33-86 are in condition for allowance. Thus, Applicant respectfully requests timely issuance of a Notice of Allowance.

Please grant any extensions of time required to enter this response. A check for $812.00 is enclosed to cover the fee for the added claims, two extensions of time, and a Supplementary Information Disclosure Statement. Please charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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By: 
Deborah J. Acker
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Dated: December 20, 2002

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Appendix - Marked-up copy of title

Please amend the title as shown below:

TREATMENT OR PREVENTION OF MENOPAUSAL SYMPTOMS [AND OSTEOPOROSIS]

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